

In the Claims

Claim 1 (Currently amended): A method for modulating an immune response, comprising administering to a patient an effective amount of a nucleic acid sequence encoding IL-12, and an operably linked promoter sequence; and an effective amount of a nucleic acid sequence encoding IFN- $\gamma$ , and an operably linked promoter sequence; ~~to a patient in need thereof~~, resulting in an increase of Th1-type cytokine production and a decrease of Th2-type cytokine production within the patient.

Claim 2 (Previously presented): The method of claim 1, wherein the IL-12 is human IL-12, and wherein the IFN- $\gamma$  is human IFN- $\gamma$ .

Claim 3 (Previously presented): The method of claim 1, wherein the IL-12 comprises the p35 subunit and the p40 subunit, wherein the p35 subunit comprises the amino acid sequence of SEQ ID NO:8, and wherein the p40 subunit comprises the amino acid sequence of SEQ ID NO:10.

Claim 4 (Currently amended): The method of claim 1, wherein the IL-12 comprises ~~the~~ a p35 subunit and a p40 subunit, wherein the p35 subunit is operably linked to a promoter sequence, and wherein the p40 subunit is operably linked to a promoter sequence.

Claim 5 (Cancelled)

Claim 6 (Previously presented): The method of claim 1, wherein the IFN- $\gamma$  comprises the amino acid sequence of SEQ ID NO:12.

Claim 7 (Previously presented): The method of claim 1, wherein the nucleic acid sequence encoding IL-12 comprises SEQ ID NO:7 and SEQ ID NO:9.

Claim 8 (Previously presented): The method of claim 1, wherein the nucleic acid sequence encoding IFN- $\gamma$  comprises SEQ ID NO:11.

Claim 9 (Previously presented): The method of claim 1, wherein the nucleic acid sequences are administered with a pharmaceutically acceptable carrier.

Claim 10 (Cancelled)

Claim 11 (Previously presented): The method of claim 1, wherein the nucleic acid sequences are administered within separate DNA plasmids.

Claim 12 (Previously presented): The method of claim 1, wherein the nucleic acid sequences and promoter sequences are administered within a viral vector.

Claim 13 (Cancelled)

Claim 14 (Original): The method of claim 1, further comprising administering an antigen to the patient.

Claim 15 (Original): The method of claim 14, wherein the antigen is selected from the group consisting of a protein, peptide, glycoprotein, carbohydrate, lipid, glycolipid, hapten conjugate, recombinant nucleotides, killed or attenuated organism, toxin, toxoid, and organic molecule.

Claims 16-17 (Cancelled)

Claim 18 (Previously presented): The method of claim 14, wherein the antigen is administered to the patient with the nucleic acid sequences and a pharmaceutically acceptable carrier.

Claim 19 (Original): The method of claim 1, wherein the patient is human.

Claim 20 (Previously presented): A pharmaceutical composition comprising a nucleic acid sequence encoding IL-12 and an operably linked promoter sequence; a nucleic acid sequence encoding IFN- $\gamma$  and an operably linked promoter sequence; and a pharmaceutically acceptable carrier.

Claim 21 (Previously presented): The pharmaceutical composition of claim 20, wherein said IL-12 is human IL-12, and wherein said IFN- $\gamma$  is human IFN- $\gamma$ .

Claim 22 (Cancelled)

Claim 23 (Previously presented): The pharmaceutical composition of claim 20, wherein said IL-12 comprises a p35 subunit and a p40 subunit, wherein the said p35 subunit comprises the amino acid sequence of SEQ ID NO:8, and wherein said p40 subunit comprises the amino acid sequence of SEQ ID NO:10.

Claim 24 (Previously presented): The pharmaceutical composition of claim 20, wherein said IFN- $\gamma$  comprises the amino acid sequence of SEQ ID NO:12.

Claim 25 (Previously presented): The pharmaceutical composition of claim 20, wherein said nucleic acid sequence encoding IL-12 comprises SEQ ID NO:7 and SEQ ID NO:9.

Claim 26 (Previously presented): The pharmaceutical composition of claim 20, wherein said nucleic acid sequence encoding IFN- $\gamma$  comprises SEQ ID NO:11.

Claim 27 (Previously presented): The pharmaceutical composition of claim 20, wherein said composition comprises an expression vector containing said nucleic acid sequences and said promoter sequences.

Claim 28 (Previously presented): The pharmaceutical composition of claim 20, wherein said nucleic acid sequences are contained within separate DNA plasmids.

Claim 29 (Previously presented): The pharmaceutical composition of claim 20, wherein said nucleic acid sequences and said promoter sequences are contained within a viral vector.

Claim 30 (Original): The pharmaceutical composition of claim 20, wherein said composition further comprises an antigen.

Claim 31 (Original): The pharmaceutical composition of claim 30, wherein said antigen is selected from the group consisting of a protein, peptide, glycoprotein, carbohydrate, lipid, glycolipid, hapten conjugate, recombinant nucleotides, killed or attenuated organism, toxin, toxoid, and organic molecule.

Claims 32-42 (Cancelled)

Claim 43 (Currently amended): A method for modulating an immune response, comprising administering to a patient an effective amount of a plasmid comprising a nucleic acid sequence encoding IL-12, and an operably linked promoter sequence; and an effective amount of a plasmid comprising a nucleic acid sequence encoding IFN- $\gamma$ , and an operably linked promoter sequence, resulting in an increase of Th1-type cytokine production and a decrease of Th2-type cytokine production within the patient.

Claim 44 (Previously presented): The method of claim 43, further comprising administering an antigen to the patient.

Claim 45 (Previously presented): The method of claim 44, wherein the antigen is an allergen.

Claim 46 (Previously presented): The method of claim 44, wherein the antigen comprises Kentucky blue grass (KBG) allergen extract.

Claim 47 (Previously presented): The method of claim 43, wherein the operably linked promoters are cytomegalovirus (CMV) promoters.

Claim 48 (Previously presented): The method of claim 44, wherein the antigen comprises Kentucky blue grass (KBG) allergen extract, and wherein the operably linked promoters are cytomegalovirus (CMV) promoters.

Claim 49 (Previously presented): The method of claim 43, wherein the patient is human.

Claim 50 (Previously presented): The method of claim 43, wherein the IL-12 comprises the amino acid sequences of SEQ ID NO: 8 and SEQ ID NO:10, and wherein the IFN- $\gamma$  comprises the amino acid sequence of SEQ ID NO:12.

Claim 51 (Previously presented): The method of claim 43, wherein said administering further results in reduced serum IgE levels and increased IgG2a levels within the patient.

Claim 52 (Previously presented): The method of claim 43, wherein the patient suffers from a condition selected from the group consisting of allergy, allergic rhinitis, atopic dermatitis, asthma, allergic sinusitis, pulmonary fibrosis, and cancer.

Claim 53 (Previously presented): The method of claim 43, further comprising administering an antigen to the patient, wherein the plasmids are administered by a route selected from the group consisting of intramuscularly, orally, and intranasally.

Claim 54 (Previously presented): A pharmaceutical composition comprising a plasmid comprising a nucleic acid sequence encoding IL-12, and an operably linked promoter; a plasmid

comprising a nucleic acid sequence encoding IFN- $\gamma$  and an operably linked promoter; and a pharmaceutically acceptable carrier.

Claim 55 (Previously presented): The pharmaceutical composition of claim 54, wherein said composition further comprises an antigen.

Claim 56 (Previously presented): The pharmaceutical composition of claim 55, wherein said antigen is an allergen.

Claim 57 (Previously presented): The pharmaceutical composition of claim 54, wherein said IL-12 comprises the amino acid sequences of SEQ ID NO: 8 and SEQ ID NO:10, and wherein said IFN- $\gamma$  comprises the amino acid sequence of SEQ ID NO:12.

Claim 58 (New): The method of claim 1, wherein the nucleic acid sequence encoding IL-12 and the nucleic acid sequence encoding IFN- $\gamma$  are administered to the patient through a mucosal route.

Claim 59 (New): The method of claim 14, wherein the nucleic acid sequence encoding IL-12 and the nucleic acid sequence encoding IFN- $\gamma$  are administered to the patient through a mucosal route.

Claim 60 (New): The method of claim 1, wherein the nucleic acid sequence encoding IL-12 and the nucleic acid sequence encoding IFN- $\gamma$  are administered to the patient intranasally.

Claim 61 (New): The method of claim 14, wherein the nucleic acid sequence encoding IL-12 and the nucleic acid sequence encoding IFN- $\gamma$  are administered to the patient intranasally.

Claim 62 (New): The method of claim 43, wherein the plasmids are administered to the patient through a mucosal route.

Claim 63 (New): The method of claim 44, wherein the plasmids are administered to the patient through a mucosal route.

Claim 64 (New): The method of claim 43, wherein the plasmids are administered to the patient intranasally.

Claim 65 (New): The method of claim 44, wherein the plasmids are administered to the patient intranasally.